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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,914	03/08/2002	Michihiro Saito	H-1036	1301

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EXAMINER

HAQ, SHAFIQU

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,914

Applicant(s)

SAITO ET AL.

Examiner

Shafiqul Haq

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 2, 4 and 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/26/2002</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

1. Claims 4-5 are objected to because of the following informalities: a grammatical error: "and" in line 3 of claims 4 and 5 should be --with-- to provide correct meaning of the sentence. Appropriate correction is required.
2. Claims 2 is objected to because of the following informalities: "reagent vessel" in line 12 should be "reaction vessel" to provide correct meaning of the sentence.
3. Claims 4-5 are objected to as the preamble reads the limitation of the claims and thus needs a transitional phrase "comprising" to separate preamble from the body of the claims.
4. Foreign patent document cited in IDS has not been considered because a copy of English translation was not supplied.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 2-3 recites the phrase "plural kinds of liquid reagent". It is not clear what is meant by the phrase. Is it the same reagent or different reagents in different reagent vessels?

Claim 1, line 3 recites the term "fine particles". It is unclear what is meant by this term as "Fine particle" is a general term encompassing different kinds and different sizes of particles and thus renders the claim indefinite.

In Claim 1, Line 5 the phrase "stirring vessel for stirring the liquid reagent" is vague and indefinite as it is unclear whether the stirring vessel performs the stirring/mixing function by itself or it requires a stirring rod. It is noted that a "stirring rod" is specifically required in the specification at page 4, line 16 and page 5, line 24.

Lines 5-8 and 11-12 of claims 1 refers to "the liquid reagent". It is not clear what liquid reagent it is referring to since lines 2-3 of claims 1 recites the phrase "plural kinds of liquid reagent". Clarification is required.

In Claim 1, line 12 the term "the reagent vessel" renders the claim indefinite as it is unclear whether the term "the reagent vessel" encompass one or more of the reagent vessels. It is noted that line 2 of claim 1 recites the phrase "plural reagent vessels".

The term "stirring time interval" in lines 14-15 of claim 1 is vague and indefinite as it is not clear what is meant by stirring time interval and how it is determined. Specification (page 3, lines 2-7) refers to a Japanese Patent for setting a "standard stirring interval" however the term has not been defined in the specification.

6. Although specific claims may be discussed in the rejections above, these rejections are also applicable to all other claims in which the noted problems/language occur.
7. Claim 2 recites the limitation "the dispensing sequence" in line 11. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 3 recites the limitation "the timing of dispensing" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 3 is rejected under 35 U.S.C. 102(b) as being anticipated by William J. Raymoure (WO 93/20444).

Raymore teaches a method for providing homogeneous reagents using automated analytical system which involves antigen or antibody bonded with fine particles (beads or particles) to determine the presence or amount of an analyte or an antibody present in a test sample (Claims 3-6 and 18). The system comprises the following: reagent vessels for liquid reagents, a reaction vessel for mixing, a probe (transfer pipette) for dispensing liquid reagent (page 28, lines 5-16 and page 22, lines 11-20) and measuring device to measure the reaction

(Page 19, lines 30-37). Raymoure also discloses that the system includes a controlled environment for providing timing of mixing (page 22, lines 18-20) and timing of dispensing (Page 28, lines 12-16) of liquid reagents.

Allowable Subject Matter

7. Claims 1-2 and 4-5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
8. The closest prior art (WO 93/20444) teaches method for providing homogeneous reagent that involves antigen or antibody bonded with fine particles and contains all the elements of the analyzing apparatus of the instant invention as discussed above for claim 3 except that the prior art fails to teach means for determining as to whether or not the liquid reagents in reagent vessels is stirred prior to dispensing based on two information: 1) predetermined stirring time interval and 2) carry-over (contamination) between liquid reagents.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax

Art Unit: 1641

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shafiqul Haq
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/17/05